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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 09/699,224 | 10/27/2000 | Peter A. Rice | BOS/3 | 8386 |
| 1473 | 7590 | 03/12/2004 | EXAMINER | |
| FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105 | | | DEVI, SARVAMANGALA J N | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/699,224

Applicant(s)

RICE ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): See attachment.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 16.

Claim(s) objected to: _____.

Claim(s) rejected: 1-10, 12, 13 and 15.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

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ATTACHMENT TO ADVISORY ACTION

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' after-final amendment filed 02/12/04 in response to the final Office Action mailed 11/12/03.

Status of Claims

- 2) Claims 2, 9, 12, 13 and 15 have been amended via the amendment filed 02/12/04.
Claims 11 and 14 have been canceled via the amendment filed 02/12/04.
Claims 1-10, 12, 13 and 15-31 are pending.
Claims 1-10, 12, 13, 15 and 16 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

- 5) The objection to the drawings made in paragraph 6 of the Office Action mailed 02/26/03 (paper no. 13) under 37 C.F.R. 1.84 is maintained for reasons set forth therein.

Rejection(s) Moot

- 6) The rejection of claim 14 made in paragraph 12(c) of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 14 of the Office Action mailed 11/12/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.
- 7) The rejection of claims 11 and 14 made in paragraph 10 of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 12 of the Office Action mailed 11/12/03 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of the US patent 5,476,784 ('784); claims 1-9 and 11 of US patent 5,939,067 (Rice *et al.*) ('067), and claims 1-4 of the US patent 6,099,839 (Rice *et al.*) ('839), is moot in light of Applicants' cancellation of the claims.
- 8) The rejection of claims 11 and 14 made in paragraph 15 of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 19 of the Office Action mailed 11/12/03 under 35 U.S.C. § 102(e) or 102(a) as being anticipated by Rice *et al.* (US 5,939,067) ('067), is moot in light of Applicants' cancellation

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of the claims.

9) The rejection of claims 11 and 14 made in paragraph 16 of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 20 of the Office Action mailed 11/12/03 under 35 U.S.C. § 102(b) as being anticipated by Rice *et al.* (US 5,476,784) ('784), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

10) The rejection of claim 9 made in paragraph 12(c) of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 14 of the Office Action mailed 11/12/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 13 made in paragraph 12(b) of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 13 of the Office Action mailed 11/12/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

12) The rejection of claims 1, 3, 9, 10, 12, 13 and 15 made in paragraph 10 of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 12 of the Office Action mailed 11/12/03 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of the US patent 5,476,784 ('784); claims 1-9 and 11 of US patent 5,939,067 (Rice *et al.*) ('067), and claims 1-4 of the US patent 6,099,839 (Rice *et al.*) ('839), is maintained for reasons set forth therein and below under paragraph 17.

13) The rejection of claim 2 made in paragraph 12(d) of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 15 of the Office Action mailed 11/12/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants state that they have amended the claim to indicate that the sequence 'DE_GLF' refers to SEQ ID NO: 8. Applicants submit that the Sequence Listing makes clear that '_' refers to any amino acid.

Applicants' argument has been considered, but is non-persuasive. The limitation '_' is inconsistent with what is recited in the Sequence Listing. Since the sequence in the amended claim is now identified by the sequence identifier 'SEQ ID NO: 8', it is suggested that Applicants replace the limitation "the sequence DE_GLF (SEQ ID NO: 8)" with --SEQ ID NO: 8--.

14) The rejection of claim 6 made in paragraph 12(e) of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 16 of the Office Action mailed 11/12/03 under 35 U.S.C. § 112, second

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paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants contend that because the inventor is permitted to define the claim terms in the specification, one of skill in the art would understand 'tail' to refer to what is described at page 19, lines 23-27. Applicants state that the term would be understood by the skilled artisan, in the context of this application, to refer to any structure that facilitates coupling of a peptide mimic to a second agent such as an adjuvant or carrier protein.

Applicants' arguments have been carefully considered, but are non-persuasive. The paragraph at page 19, lines 23-27 of the specification does not 'define' the term 'tails', but merely states that cyclic peptide mimics comprise one or more "tails" for coupling to a second agent, such as an adjuvant or a carrier protein. From this mentioning of the term, one cannot envisage the metes and bounds of the limitation in terms of its composition, its size or length, its biological or non-biological nature. What is encompassed within the scope of the term 'tails' is still not clear.

15) The rejection of dependent claims 4-10 and 15 made in paragraph 12(f) of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 17 of the Office Action mailed 11/12/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

16) The rejection of claims 1, 3, 9, 10, 12 and 13 made in paragraph 15 of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 19 of the Office Action mailed 11/12/03 under 35 U.S.C. § 102(e) or 102(a) as being anticipated by Rice *et al.* (US 5,939,067) ('067), is maintained for reasons set forth therein and herebelow under paragraph 17.

17) The rejection of claims 1, 3, 9, 10, 12 and 13 made in paragraph 16 of the Office Action mailed 02/26/03 (paper no. 13) and maintained in paragraph 20 of the Office Action mailed 11/12/03 under 35 U.S.C. § 102(b) as being anticipated by Rice *et al.* (US 5,476,784) ('784), is maintained for reasons set forth therein and herebelow.

Applicants contend that anticipation of a claim requires that the prior art reference teach every element of the claim. Applicants state that claim 1 is not directed simply to a peptide mimic but to a peptide mimic that is capable of inducing in a mammal an immune response against a conserved gonococcal epitope. Applicants submit that none of the cited references, the '839, '067 and '784 patents, teach anti-idiotypic antibody fragments that are capable of inducing such an immune response. Applicants assert that binding to an epitope does not necessarily result in induction of an immune response. Applicants further argue that none of the prior art antibody fragments are demonstrated to be capable of eliciting an immune response.

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Applicants' arguments have been carefully considered, but are non-persuasive. Applicants are correct in that, to anticipate a claim, a prior art reference must teach, either *expressly* or *inherently*, each and every element of the claim. See *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631 (Fed. Cir. 1987). As set forth previously, the cited prior art patents taught anti-idiotypic antibody fragments of the same specificity. One of skill in the art would reasonably expect an antibody fragment long enough to contain an antigen-binding site to have the capability to induce an immune response. That the prior art binding fragments, long enough to contain the antigen binding site, intrinsically serve as peptide mimics being capable of inducing an immune response is evident from the teachings of Rice *et al.* These patents expressly disclosed that anti-idiotypic antibody fragments that react with an idiotypic antigen that is directed against an oligosaccharide antigen of *N. gonorrhoeae* is administered to individuals 'to induce a specific immune response directed against gonococcal organisms', and that such an immunoprophylactic response would prevent a gonococcal infection. See third full paragraph in column 7 of '839, '067 and '784 patents. Furthermore, each of the three applied patents expressly taught that Ab2 or Ab3 (i.e., anti-idiotypic antibody) fragment of the invention is used as an 'immunogen' in the treatment of patients infected with *N. gonorrhoeae*. See fourth full paragraph in column 7 of the '839, '067 and '784 patents. The claims of the '839 patent specifically claimed a composition comprising an antigen binding fragment of the anti-idiotypic monoclonal antibody 'for immunizing against *N. gonorrhoeae* infection'. Thus, the *prima facie* evidence that the prior art peptide mimic is capable of eliciting an immune response in a mammal comes from the prior art patents themselves. The rejections stand.

Remarks

18) Claims 1-10, 12, 13 and 15 stand rejected. Claim 16 is free of prior art currently of record and is allowable.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15

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a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March, 2004

SD-Marchof
S. DEVI, PH.D.
PRIMARY EXAMINER